

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Hayes *et al.*

Serial No.:

Group No.: not yet assigned

Filed: 12/21/99

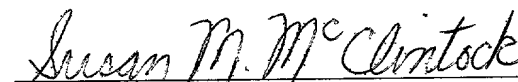
Examiner: not yet assigned

Entitled: **Use of Biologically Active Vitamin D Compounds for the Prevention and Treatment of Inflammatory Bowel Disease****PRELIMINARY AMENDMENT**Assistant Commissioner for Patents
Washington, D.C. 20231**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)**

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EL 837 033 658 US, addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Dated: December 21, 2001

By:


Susan M. McClintock

Sir or Madam:

Prior to the examination of this Application, Applicants respectfully request that the following amendments be entered.

IN THE SPECIFICATION:

On page 1, on line 3, please insert --The present Application is a Continuation of copending application Serial No. 09/469,985, filed December 21, 1999, which is allowed.--.

IN THE CLAIMS:

Please cancel Claims: 1-20.

Please add the following New Claims:

21. (new) A method of treatment, comprising:
- a) providing:
 - i) a subject with symptoms of an inflammatory bowel disease, wherein said inflammatory bowel disease is selected from the group consisting of ulcerative colitis and crohn's disease, and
 - ii) a therapeutic composition comprising a biologically active vitamin D compound, wherein said biologically active vitamin D compound is 1α -hydroxyvitamin D₃; and
 - b) administering a therapeutically effective amount of said therapeutic composition to said subject under conditions such that said symptoms are reduced.
22. (new) The method of Claim 21, wherein said therapeutically effective amount comprises a daily dose of between 0.1 μ g and 20 μ g per 160 pounds of said subject.
23. (new) The method of Claim 21, wherein said therapeutically effective amount comprises a daily dose of between 0.5 μ g and 10 μ g per 160 pounds of said subject.
24. (new) The method of Claim 21, wherein said therapeutically effective amount comprises a daily dose of between 3.0 μ g and 10 μ g per 160 pounds of said subject.
25. (new) The method of Claim 21, wherein said administering is conducted in a continuous manner.
26. (new) The method of Claim 21, wherein said administering is via a transdermal patch.
27. (new) The method of Claim 21, wherein said administering is via a suppository.
28. (new) The method of Claim 21, wherein said administering is via a slow release oral formulation.

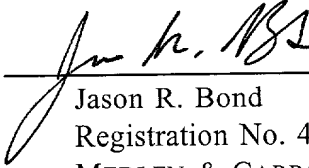
29. (new) A method of treatment, comprising:
- a) providing:
 - i) a subject with symptoms of an inflammatory bowel disease, wherein said inflammatory bowel disease is selected from the group consisting of ulcerative colitis and crohn's disease, and
 - ii) a therapeutic composition comprising a biologically active vitamin D compound, wherein said biologically active vitamin D compound is 1α -hydroxyvitamin D₂; and
 - b) administering a therapeutically effective amount of said therapeutic composition to said subject under conditions such that said symptoms are reduced.
30. (new) The method of Claim 29, wherein said therapeutically effective amount comprises a daily dose of between 0.1 µg and 20 µg per 160 pounds of said subject.
31. (new) The method of Claim 29, wherein said therapeutically effective amount comprises a daily dose of between 0.5 µg and 10 µg per 160 pounds of said subject.
32. (new) The method of Claim 29, wherein said therapeutically effective amount comprises a daily dose of between 3.0 µg and 10 µg per 160 pounds of said subject.
33. (new) The method of Claim 29, wherein said administering is conducted in a continuous manner.
34. (new) The method of Claim 29, wherein said administering is via a transdermal patch.
35. (new) The method of Claim 29, wherein said administering is via a suppository.
36. (new) The method of Claim 29, wherein said administering is via a slow release oral formulation.

37. (new) A method of treatment, comprising:
- a) providing:
 - i) a subject with symptoms of an inflammatory bowel disease, wherein said inflammatory bowel disease is selected from the group consisting of ulcerative colitis and crohn's disease, and
 - ii) a therapeutic composition comprising a biologically active vitamin D compound, wherein said biologically active vitamin D compound is 19-nor-1 α ,25-dihydroxyvitamin D₂; and
 - b) administering a therapeutically effective amount of said therapeutic composition to said subject under conditions such that said symptoms are reduced.
38. (new) The method of Claim 37, wherein said therapeutically effective amount comprises a daily dose of between 0.1 μ g and 20 μ g per 160 pounds of said subject.
39. (new) The method of Claim 37, wherein said therapeutically effective amount comprises a daily dose of between 0.5 μ g and 10 μ g per 160 pounds of said subject.
40. (new) The method of Claim 37, wherein said therapeutically effective amount comprises a daily dose of between 3.0 μ g and 10 μ g per 160 pounds of said subject.
41. (new) The method of Claim 37, wherein said administering is conducted in a continuous manner.
42. (new) The method of Claim 37, wherein said administering is via a transdermal patch.
43. (new) The method of Claim 37, wherein said administering is via a suppository.
44. (new) The method of Claim 37, wherein said administering is via a slow release oral formulation.

REMARKS

Claims 1-20 were filed in the accompanying Continuation Application. The above amendment cancels Claims 1-20, and adds new Claims 21-44. As such, Claims 21-44 are currently pending in this Application.

Dated: December 21, 2001



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1003619-133401
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PENDING CLAIMS

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- a) providing:
 - i) a subject with symptoms of an inflammatory bowel disease, wherein said inflammatory bowel disease is selected from the group consisting of ulcerative colitis and crohn's disease, and
 - ii) a therapeutic composition comprising a biologically active vitamin D compound, wherein said biologically active vitamin D compound is 1α -hydroxyvitamin D_3 ; and
 - b) administering a therapeutically effective amount of said therapeutic composition to said subject under conditions such that said symptoms are reduced.
22. The method of Claim 21, wherein said therapeutically effective amount comprises a daily dose of between 0.1 μg and 20 μg per 160 pounds of said subject.
23. The method of Claim 21, wherein said therapeutically effective amount comprises a daily dose of between 0.5 μg and 10 μg per 160 pounds of said subject.
24. The method of Claim 21, wherein said therapeutically effective amount comprises a daily dose of between 3.0 μg and 10 μg per 160 pounds of said subject.
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28. The method of Claim 21, wherein said administering is via a slow release oral formulation.

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- a) providing:
 - i) a subject with symptoms of an inflammatory bowel disease, wherein said inflammatory bowel disease is selected from the group consisting of ulcerative colitis and crohn's disease, and
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 - b) administering a therapeutically effective amount of said therapeutic composition to said subject under conditions such that said symptoms are reduced.
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 - i) a subject with symptoms of an inflammatory bowel disease, wherein said inflammatory bowel disease is selected from the group consisting of ulcerative colitis and crohn's disease, and
 - ii) a therapeutic composition comprising a biologically active vitamin D compound, wherein said biologically active vitamin D compound is 19-nor-1 α ,25-dihydroxyvitamin D₂; and
 - b) administering a therapeutically effective amount of said therapeutic composition to said subject under conditions such that said symptoms are reduced.
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44. The method of Claim 37, wherein said administering is via a slow release oral formulation.